UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

CHRISTINE DELEON, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. C-11-177
	§	
JOHNSON & JOHNSON, *et al*,	§	
	§	
Defendants.	§	

ORDER

Pending before the Court is Defendant DePuy Orthopaedics, Inc.'s Rule 12(b)(6) Motion to Dismiss. (D.E. 4.) Plaintiffs failed to respond to the motion, so it is deemed unopposed. L.R. 7.4. Regardless, the Court has reviewed the motion, the record, and the applicable law. For the reasons stated herein, the motion is GRANTED. This action is dismissed with prejudice as to both Defendants.

I. Jurisdiction

The Court has diversity jurisdiction under 28 U.S.C. § 1332 as the parties are completely diverse and Plaintiffs allege over $75,000 in damages. Plaintiffs filed suit in the 148th Judicial District Court of Nueces County, Texas on April 22, 2011. Defendant DePuy Orthopaedics, Inc. was served on May 10, 2010 and timely removed the action to this Court on May 31, 2011 alleging diversity jurisdiction.[1]

II. Background

On April 22, 2011, Plaintiffs Christine DeLeon and Higinio DeLeon, Jr.

[1] Service on Defendant Johnson & Johnson was not effectuated, (D.E. 1, Ex. C (May 10, 2011 letter returning service of process)), and so it did not join in the removal. See Getty Oil Corp. v. Ins. Co. of N. Am., 841 F.2d 254, 1261 (5th Cir. 1988) (those named as defendants but not yet served in the state court action need not join in the removal).

("Plaintiffs") filed an original petition against DePuy Orthopaedics and Johnson & Johnson (collectively, "Defendants"), alleging that on September 4, 2007 "Plaintiff Christine DeLeon received a Charite artificial disc manufactured and sold by the Defendants for replacement of her natural L5-S1 disc" and that thereafter she suffered from acute and constant pain at all levels of her spine, necessitating the disc's removal on July 29, 2010. (D.E. 1, Ex. B at 2.) Prior to and after the surgery she has suffered from constant pain and takes morphine six times a day. She alleges that, because of the Charite disc, she has had multiple back surgeries and continues to have "severe chronic pain" in her back. (Id.)

Plaintiffs assert the following causes of action under Texas law against DePuy Orthopaedics, Inc. and Johnson & Johnson: (1) products liability; (2) deceptive trade practices[2]; (3) negligence; and (4) gross negligence. Plaintiff Christine DeLeon seeks actual and exemplary damages. Plaintiff Higinio DeLeon, Jr. seeks damages for loss of consortium and loss of household services. (Id. at 2-3.)

Defendant DePuy Orthopaedics, Inc. moves to dismiss Plaintiffs' claims under Rule 12(b)(6) as preempted by federal law. (D.E. 4.) Plaintiffs have failed to respond to the motion, so it is deemed unopposed. L.R. 7.4.

III. Discussion

A. Motion to Dismiss

"To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief – including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.'" Cuvillier v. Sullivan, 503 F.3d 397, 401 (5th Cir. 2007.) (citing Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1964-65 (2007)). "Conversely, 'when the allegations in a complaint,

[2] Plaintiff presumably brings this claim under the Texas Deceptive Trade Practices Act ("DTPA").

however true, could not raise a claim of entitlement to relief, this basic deficiency should … be exposed at the point of minimum expenditure of time and money by the parties and the court.'" Cuvillier, 503 F.3d at 401 (citing Twombly, 127 S.Ct. at 1966 (internal citations and quotations omitted)).

In deciding a motion to dismiss "[w]e must accept all well-pleaded facts alleged in the complaint as true and must construe the allegations in the light that is most favorable to the plaintiff." Cent. Laborers' Pension Fund v. Integrated Elec. Servs., 497 F.3d 546, 550 (5th Cir. 2007) (citing Plotkin v. IP Axess Inc., 407 F.3d 690, 696 (5th Cir. 2005)). "Nevertheless, '[w]e do not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions.'" Id.

B. Analysis

Defendant claims that Plaintiffs' state-law claims for products liability, deceptive trade practices, negligence and gross negligence are preempted in their entirety by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 301 et seq., to the Federal Food, Drug, and Cosmetics Act of 1938 ("FDCA"), 52 Stat. 1040, as construed by the Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).

The MDA's express preemption provision, 21 U.S.C. § 360K(a), provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Fifth Circuit recently explained the effect of the MDA's preemption provision, as construed by the Supreme Court in Riegel, on state-law tort claims. See Hughes v. Boston

Scientific Corp., 631 F.3d 762, 767 (5th Cir. 2011). The court stated: "Riegel, like the Court's earlier decision in Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996), makes clear that a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations." Id.[3]

The Fifth Circuit further explained that, under Riegel, there is a two-prong test for determining if a state-law tort claim is preempted by § 360k. See id. "First, we ask if the FDA has established requirements applicable to the particular device at issue. Second, we ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is 'different from or in addition to' the federal requirement.'" Id. at 767-768 (quoting Riegel, 552 U.S. at 322.) "[S]tate common-law causes of action are considered 'requirements' under this test that cannot vary from federal requirements pursuant to § 360k." Id. at 768. "Specifically," in Riegel, "the Court held that New York common-law tort claims of negligence, strict liability, and breach of warranty imposed requirements that were preempted by federal requirements pertaining to medical devices to the extent that these state tort claims required the device 'to be safer, but hence less effective, than the model the FDA has approved. . . .'" Id. (quoting 552 U.S. at 325.)

Applying Riegel's two-prong test for express preemption to Plaintiffs' claims, we first ask whether the FDA has established requirements applicable to the particular device at issue. Riegel, 552 U.S. at 322. Here, the Charite disk that allegedly caused Plaintiff Christine DeLeon's injuries is a Class III device that was subjected to and approved under the Food and

[3] The court went on to note that "Riegel and Lohr also make clear that a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements." Id. However, here, Plaintiffs' claims are not premised on any violation of the applicable federal requirements.

Drug Administration ("FDA") premarketing approval ("PMA") process.[4] "Riegel established that any Class III device receiving PMA approval by the FDA will satisfy this first prong of the test[.]" Hughes, 631 F.3d at 768 (citing Riegel, 552 U.S. at 322.) Thus, the Court concludes the first prong is satisfied.

Moving to the second prong of the test, the Court must ask whether the state law at issue creates a "requirement" that is related to the device's safety or effectiveness and is "different from or in addition to" a federal requirement. Id. (citing Riegel, 552 U.S. at 322.) The Court finds all of Plaintiffs' state law claims that purport to impose liability on Defendants despite their compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted. See id. at 769. The Fifth Circuit had "held such traditional state products liability claims to be expressly preempted even prior to Riegel's confirmation that these types of claims may not be maintained under § 360k." Id. (citing Gomez v. St. Jude Medical Daig. Div.,

[4] As the Fifth Circuit explained:

> Class III devices are those that either "presen[t] a potential unreasonable risk of illness or injury" or are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). As part of the PMA approval process, manufacturers of Class III devices must provide the FDA with a "reasonable assurance" that the device is both safe and effective. Id. § 360e(d)(2). The applicant must submit detailed information including full reports of all relevant information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. Id. § 360e(c)(1). In its review, the agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Id. § 360c(a)(2)(C). Once a device has received PMA approval, the manufacturer cannot make changes to any feature of the device without obtaining FDA permission. Id. § 360e(d)(6).
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> After PMA approval, manufacturers of Class III devices must comply with Medical Device Reporting ("MDR") requirements. Id. § 360i(a)(1); 21 C.F.R. § 803.50(a). The FDA may approve marketing of the Class III device subject to additional postapproval conditions, which the FDA may include in its PMA approval order. See 21 U.S.C. §§ 360c-360j; 21 C.F.R. §§814.80, 814.82. If a manufacturer fails to comply with the FDA regulations or postapproval conditions, the FDA has the power to withdraw PMA approval, as well as the power to impose other remedies such as additional warnings or corrective labeling. See 21 U.S.C. §§ 351, 352, 360(h), 374.

Hughes, 631 F.3d at 764-765.

Inc., 442 F.3d 919, 930-31 (5th Cir. 2006); Martin v. Medtronic, Inc., 254 F.3d 573, 575 (5th Cir. 2001).)

Because all of Plaintiffs' claims — for products liability, negligence, gross negligence, and deceptive trade practices — are preempted under 21 U.S.C. § 360k, Plaintiffs fail to state a claim upon which relief can be granted, and Defendant's motion to dismiss Plaintiffs' claims is therefore granted. See Hughes, 631 F.3d at 768 (citing Riegel, 552 U.S. at 322); see also Timberlake v. Synthes Spine, Inc., 2011 U.S. Dist. LEXIS 17034, * 36-37 (S.D. Tex. Feb. 18, 2011) (plaintiff's claims for, inter alia, strict liability and negligence based on alleged failure of spinal disc preempted by MDA); Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 657 (S.D. Tex. 2010) (dismissing on 12(b)(6) plaintiff's for strict liability, negligence, and deceptive trade practices) (citing Worthy v. Collagen Corporation, 967 S.W.2d 360, 376-377 (Tex. 1998)); Funk v. Stryker Corp., 673 F. Supp. 2d 522, 532 (S.D. Tex. 2009) (dismissing on 12(b)(6) plaintiff's strict liability, negligence, and Texas Deceptive Trade Practices Act claims based on alleged injury from a defective hip implant as preempted under the MDA); Miller v. DePuy Spine, Inc., 638 F. Supp. 2d 1226, 1231 (D. Nev. 2009) (dismissing on summary judgment plaintiff's product liability, negligence, and breach of warranties claims against DePuy Spine, Inc. based on allegedly defective Charite disc as preempted under the MDA).

IV. Conclusion

For the reasons stated above, the Court GRANTS Defendant's Motion to Dismiss. (D.E. 4.) This action is dismissed with prejudice as to all Defendants.

SIGNED and ORDERED this 1st day of July, 2011.

Janis Graham Jack
United States District Judge